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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/900,707	07/06/2001	Roger E. Darois	D0188/7126	4890

7590 06/30/2008
Jason M. Honeyman
Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, MA 02210

EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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06/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/900,707	Applicant(s) DAROIS ET AL.	
	Examiner Brian E. Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14/08, 4/18/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 46,53,54,59,60,65,66,71 are rejected under 35 U.S.C. 102(e) as being anticipated by Ory et al. (6264702). Fig. 1 shows an implantable repair fabric having a layer of mesh fabric (2) with a plurality of interstices constructed to allow tissue ingrowth and also including an adhesion resistant barrier layer (3) that inhibits the formation of adhesions with sensitive tissues. The examiner is interpreting the claimed elements “adhesion resistant edge barrier” in this way: since the repair fabric is of a smaller dimension as seen in Fig. 1, the barrier layer that extends beyond the fabric thus forms an edge barrier that isolates "a portion of the edge" from the sensitive tissues. Claims in a pending application should be given their broadest reasonable interpretation. *In re Pearson*, 181 USPQ 641 (CCPA 1974). See also *In re Morris*, Fed. Cir. 1997 127 F3d 1048, 1054, 1055. Ory discloses that the fabric side is for tissue ingrowth and the barrier layer side is adhesion resistant, col. 4, lines 20-25.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 47-50,55,56,61,62,67,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ory et al. '702 in view of Nicolo (6652595). Ory et al. is explained supra. However, Ory et al. fail to explicitly disclose the attachment means between the barrier layer and fabric to be stitching or that the fabric material is polypropylene. Nicolo teaches that a barrier layer and fabric layer for a repair mesh is stitched together, col. 4, lines 59-60. It would have been obvious to one of ordinary skill in the art to use stitching as taught by Nicolo with the repair fabric of Ory et al. such that it prevents any separation of the two layers from prematurely separating and eliminates using adhesives that could cause irritation. With respect to claims 50,56,62,68, Nicolo teaches that polypropylene material is used for the fabric layer, col. 4, lines 20-29. It would have been obvious to one of ordinary skill in the art to use polypropylene as the fabric material as taught by Nicolo with the repair device of Ory et al. such that it is biologically accepted. Regarding claim 49, it would have been an obvious expedient to use a pair of continuous stitches with the stitch pattern in the repair fabric of Ory as modified by Nicolo since it is common sense that using multiple stitches or a pair provides greater strength.

Claims 51,52,57,58,63,64,69,70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ory et al. '702 in view of Nicolo '595 as applied to claims 46,56,62,68 above, and further in view of Eldridge et al. (6120539). Ory et al. in view of Nicolo is

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explained supra. It is noted that Nicolo does teach that PTFE can be used for the barrier material, col. 4, lines 40-42. However, Ory as modified by Nicolo fail to disclose using ePTFE. Eldridge et al. teach that the barrier layer is formed of ePTFE to discourage ingrowth, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to substitute ePTFE barrier material as taught by Eldridge with the repair fabric of Ory as modified by Nicolo since such a modification only involves routine skill in the art.

Claims 53,56,65,68,71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meier (3416524) in view of Linsky et al. (5002551). Meier shows (Fig. 2) a surgical repair material comprising a fabric **15**, a barrier layer **14** and an edge barrier **12**. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Regarding claims 56,58, Meier discloses the fabric layer can be polypropylene, col. 2, lines 1-5. Fig. 1 clearly shows a mesh structure. However, Meier is silent as to the edge barrier is adhesion resistant. Linsky et al. teach that materials contacting tissue where surgery occurs ought to be adhesion resistant, col. 1, lines 38-41. Linsky also teaches that the porosity is a factor and has a pore size that discourages tissue ingrowth in a barrier material, col. 3, lines 64-68. It would have been obvious to one of ordinary skill in the art to use material with a pore size to be adhesion resistant as taught by Linsky et al. with the surgical repair device of Meier such that it inhibits the formation of adhesions with sensitive tissues and organs in order to improve the success rate of the surgery.

Response to Arguments

Applicant's arguments with respect to claims 46,53,59,65 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738